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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,320	11/08/2001	Roman M. Barabolak	112703-211	2531

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,320

Applicant(s)

BARABOLAK ET AL.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Previous Rejections

Unless specifically repeated hereinunder, all previous rejections are withdrawn.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

Applicant states that support for the amendments made to claims 1, 6 and 15 requiring "three distinct compounds" can be found at page 10, lines 20-24 of the specification, wherein an emulsion containing triclosan, (hydroxylated) lecithin and CPC (cetyl pyridinium chloride) is disclosed. (Remarks, page 5, ¶ 2).

The specification as originally filed does not support such language, either explicitly or implicitly. The terms "emulsifier" and "surfactant" are not mutually exclusive, as the discussion provided at pages 3 and 4 of the previous Office action regarding WO 95/17159 demonstrates. The terms are merely functional descriptors and the state of the prior art is such that the very same compound can be described by two different authors as an "emulsifier" on one hand and a "surfactant" on the other. See, for example, Chemical Abstracts 119:158564 and Chemical Abstracts 116:39909, cited on the attached form 892. In

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the title of the former Tween 20 is termed an "emusifer", while in the latter it is termed a "surfactant" - this despite the fact that the utilities involved are virtually identical.

The only surfactant disclosed by the instant specification is CPC; the only emulsifier disclosed is hydroxylated lecithin. Page 11, lines 25 and 26 of the specification vaguely state that "other ionic and non-ionic surfactants may also be employed", but none are specified. Lecithin is also mentioned at page 7, line 14, but as a chewing gum base component, not a soluble emulsifier for triclosan. Given the state of the art discussed above, the mere disclosure by Applicant of two specific compounds as examples of "emulsifiers" and "surfactants" can hardly be the basis for implicit support of the broad conceptual language added to the instant claims.

Obviousness Rejections (New, Necessitated by Amendment)

1) Claims 1-5, 15, 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/17159.

The prior art has been discussed previously in detail at pages 3 and 4 of the previous Office action, and differs from the instant claims as now amended insofar as it does not specifically disclose a mixture three distinct compounds comprising an emulsifier, triclosan and a surfactant.

As discussed in the previous action at page 4, the cationic antimicrobial (e.g., CPC) of the prior art functions simultaneously as both an emulsifier and a surfactant. The prior art clearly teaches that "mixtures of cationic antimicrobials" may be used: see page; 4, lines 27 and 28. It would have been obvious to have followed this clear teaching to provide a composition comprising a combination of cationic antimicrobials, e.g., a mixture of CPC and dodecyl trimethyl ammonium bromide. This position is also fully consistent with established precedent, which holds that it is generally obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In re Kerkhoven, 205 U.S.P.Q. 1069 (CCPA 1980). The idea for combining said compositions flows logically from their having been individually taught in the prior art. In re Crockett, 126 USPQ 186, 188 (CCPA 1960). A mixture of two cationic antimicrobials

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(each of which is simultaneously both a "surfactant" and an "emulsifier") and triclosan would be a "liquid mixture comprising three distinct compounds comprising an emulsifier, triclosan and a surfactant" as instantly claimed.

2) Claims 1, 6-8, 12-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (USP 5,380,530).

The prior art has been discussed previously in detail at pages 5 and 6 of the previous Office action, and differs from the instant claims as now amended insofar as it does not specifically disclose a mixture three distinct compounds comprising an emulsifier, triclosan and a surfactant.

Applicant argues:

Hill fails to provide any motivation for [the now claimed] combination. Although the Office action indicates that Hill discloses the combination of certain surfactants and/or emulsifiers at col. 13, line 49, the referenced passage is limited to such mixtures as being advantageous when used in combination with polydimethylsiloxanes for use in coating teeth and oral surfaces to form smooth surfaces that interfered with plaque adherence. It is not apparent from this passage that there would be any advantage to the use of the same mixtures with chemically distinct compounds, such as triclosan (a derivatized diphenylether compound), so as to provide any motivation for the combination of an emulsifier and chemically distinct surfactant with triclosan as in Applicant's invention. (Remarks, page 6, ¶ 3).

The examiner does not agree. The prior art clearly discloses mixtures of surfactants, emulsifiers and polydimethylsiloxanes at col. 13, line 49. The instant claims, which employ the open-ended transitional phrase "comprising", do not exclude the presence of additional ingredients such as polydimethylsiloxanes. Thus, to arrive at the instantly claimed mixtures, all that is necessary is to select triclosan from the list of optional therapeutic agents provided at col. 15 of the prior art. Applicant's arguments to the contrary notwithstanding, there is in fact an "advantage" to including triclosan in the prior art compositions. As Applicant has pointed out, the section referenced by the examiner is specifically concerned with coating teeth and oral surfaces to form smooth surfaces that interfere with plaque adherence. The advantage of including an antiplaque agent (triclosan) for the purpose of further inhibiting plaque formation on those smooth surfaces is self-evident, and it would have been obvious to have used triclosan for that art-recognized purpose. This position is fully consistent with established precedent. See

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for example In re Dial, 326 F.2d 430, 432 (CCPA 1964). (Holding that it would have been obvious to have combined four individual stabilizers from three different references in order to obtain the art-recognized stabilizing effects expected for each individual component, absent evidence in the record that Applicant's particular combination of stabilizers was more effective at inhibiting decomposition than any single member of that combination).

3) Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/17159 in view of Gaffar (USP 5,472,685).

The primary reference has been discussed in detail above and in the previous Office action, and differs from the instant claim insofar as it discloses mouthwashes, not dentrifies such toothpastes and gels.

It is well-known in the art to administer oral care agents, and antiplaque agents such as triclosan in particular, in various types of formulations. The motivation to use one form over another, e.g. a dentrifice over a mouthwash, arises from the desire to tailor an oral hygiene regimen to the individual preferences of particular users. It is well within the ordinary skill of the oral care art to adjust between different formulations for use in this manner. See the secondary reference at col. 1, lines 12-25; the passage spanning col. 2, line 43 to col. 3, line 25; col. 6, lines 13-35; and the passage spanning col. 6, line 57 to col. 7, line 43. The secondary reference differs from the instant claims insofar as it does not specifically disclose an emulsion comprising triclosan, an emulsifier and a surfactant.

It would have been obvious to have prepared the triclosan/cationic antimicrobial mixtures of the primary reference in dentrifice (rather than mouthwash) form, motivated by the desire to tailor administration to the particular desires of individual users. (Certain users will prefer dentrifies because they permit better control over application to particular plaque forming sites within the teeth, for example).

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Obviousness Rejection (Previous)

Claims 6 and 9-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (USP 5,380,530) in view of WO 95/17159.

This rejection is maintained.

Applicant has argued that this rejection is inapposite because the primary reference is not sufficient to reject the base claims on its own, and thus cannot be used in combination with another reference to reject dependent claims. (Remarks, page 7, ¶ 1). The examiner has maintained the base rejection over the primary reference, however (see subsection "1)" of the "Anticipation" section supra), and thus maintains this derivative rejection as well, for the reasons already of record.

Obviousness-Type Double Patenting Rejection

Claims 1-22 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,436,369, taken in view of Hill (USP 5,380,530).

This rejection is maintained.

Applicant has chosen to defer submission of a terminal disclaimer until such time as allowable subject matter is indicated. (Remarks, p. 7, ¶ 2).

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date

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of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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